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PATENT SPECIFICATION

NO DRAWINGS

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International Classification: A61b. B29d.

Instrument in particular Catheter to be introduced into Body Cavities and Process and Apparatus for its Manufacture.

COMPLETE SPECIFICATION

I, WILLY RÜSCH, a German citizen, of Rommelshausen b. Stuttgart, Germany, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:

Instruments in particular catheters, bougies and the like to be introduced into body cavities, which instruments are manufactured from mineralised rubber, are already known, as also are catheters and the like manufactured from synthetic materials, preferably on the basis of polyethylenes.

The manufacture of catheters from mineralised rubber requires the use of glass moulds. After the shaping of the instruments they must be vulcanised and they are required to be comparatively resistant in a high degree to high temperature and to be elastic. Hower, if they are left in the body cavity for a long time they are attacked by chemical action and, in particular, when in contact with urine, they become encrusted both inside and outside by the urine salts whereby sharp edged cracks may occur on the upper surface of the tubes. They are therefore only usable to a limited extent as so-called "self-retaining catheters" which under certain circumstances are to remain in the body for months or years.

On the other hand, the known instruments of polyethylene and other synthetic materials are substantially indifferent to external influences. They are however not sufficiently heat resistant, they plasticise at temperatures of 100° and therefore cannot be sterilised to the required degree. These catheters also must be changed at short intervals of time as they readily produce an inflammatory area in the body. Furthermore, they do not possess the same amount of elasticity and ductility as the catheters made of mineralised rubber. They may also be attacked, like the latter, by urine salts and other chemical substances.

The subject matter of this invention is an instrument in which the drawbacks of the two known types of catheters are obviated whilst on the other hand their advantages are combined whereby the catheter is suitable mainly as a self-retaining catheter.

According to the invention, a catheter is formed of silicone rubber by injection moulding on a mandrel of wire which has a cone-shaped rear end part for forming a funnel-shaped inlet, and is adapted to form the front end to receive a closing stopper, and the moulded material is hardended without pressure at an elevated temperature in two successive stages each of comparatively long duration, for example 5 hours, the temperature during the first stage being from 180C°. to 200C°. and during the second stage from 200°C. to 250°C. By regulation of the time period, the degree of hardness and the degree of elasticity can be determined as desired. After the hardening, the core is removed and the finished product is allowed to cool without quenching.

By reason of the said hardening process the original inelastic and kneadable starting material receives the required elasticity as in the hardening of steel. The catheter according to the invention is heat resistant up to 250° so that a sufficient sterilisation is possible, as often as desired, without influencing the shape of the instrument.

The manufacture of the usual eyes and holes is effected by stamping or punching and grinding in the same manner as in the hitherto known catheters.

The invention can be used in all known shapes of catheters, bougies and similar instruments, with the same advantage.

WHAT I CLAIM IS:

1. A catheter or like instrument for introduction into body cavities, formed of silicone rubber by injection moulding on a mandrel of wire which has a cone-shaped

(Price 3s. 6d.)

rear end part for forming a funnel-shaped inlet, and is adapted to form the front end to receive a closing stopper, and which, after moulding has been hardened without pressure at an elevated temperature in two successive stages each of comparatively long duration.

2. An instrument according to claim 1 which has been hardened in a first stage at a temperature from 180°C. to 200°C. for 5 hours and in a second stage from 200°C. to 250°C. also for 5 hours.

3. Catheters, bougies and the like made substantially as herein set forth.

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